ABSTRACT

A novel crystalline form (Form H) of the aldosterone receptor antagonist drug eplerenone is provided having a relatively rapid dissolution rate in aqueous media. Also provided are novel solvated crystalline forms of eplerenone that, when desolvated, can yield Form H eplerenone. Also provided is amorphous eplerenone. Pharmaceutical compositions are provided comprising Form H eplerenone, optionally accompanied by one or more other solid state forms of eplerenone, in a total unit dosage amount of eplerenone of about 10 to about 1000 mg, and further comprising one or more pharmaceutically acceptable excipients. Processes are provided for preparing Form H eplerenone and for preparing compositions comprising Form H eplerenone. A method for prophylaxis and/or treatment of an aldosterone-mediated condition or disorder is also provided, comprising administering to a subject a therapeutically effective amount of eplerenone, wherein at least a fraction of the eplerenone present is Form H eplerenone.